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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/756,719 | 01/13/2004 | Mark E. Cook | 960296.00108 | 2648 |
| 27114 | 7590 | 01/25/2006 | EXAMINER | |
| QUARLES & BRADY LLP 411 E. WISCONSIN AVENUE, SUITE 2040 MILWAUKEE, WI 53202-4497 | | | ARNOLD, ERNST V | |
| | | | ART UNIT | PAPER NUMBER |

1616

DATE MAILED: 01/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/756,719 | COOK ET AL. | |
| | Examiner | Art Unit | |
| | Ernst V. Arnold | 1616 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>5/10/04, 5/19/05</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

The Examiner acknowledges receipt of the Applicants election without traverse of Group II claims 2 and 3 drawn a method of treating rheumatoid arthritis linked by claims 1 and 4-16 filed on 12/05/05. Accordingly, claims 1-16 are presented for examination as they read upon the elected subject matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 and 7-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Horrobin et al. (US 6,245,811).

Horrobin et al. disclose a method for treating a disorder (rheumatoid arthritis) comprising administering to a patient in need thereof an effective amount of the compound according to claim 1 where R₁ is an acyl moiety corresponding to an acid (conjugated linoleic acid) (Column 14 lines 55-62; column 15, line 1 and claims 1, 10 and 28). The Examiner interprets the compound to be an ester of conjugated linoleic acid and thus anticipate instant claim 1-5. Doses may be administered to the patient in need thereof orally, enterally, topically, parenterally, (subcutaneously, intramuscularly,

intravenously), rectally, vaginally or by any other appropriate route (Column 17, lines 32-36 and claim 28). By patient, the Examiner interprets this to be a human and thus anticipate instant claims 7-12.

Claim Rejections - 35 USC § 102

Claims 1-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Menard et al. (WO 02/09725).

Menard et al. disclose a method for treating degenerative joint disease comprising the step of administering a therapeutically effective amount of a composition comprising linoleic acid, glucosamine and ascorbic acid (claim 1). Isomers of linoleic acid are disclosed (claim 5). Menard et al. disclose that to treat rheumatoid arthritis, a daily administration of formulation will be given in an amount to provide 20 mg/kg/day conjugated linoleic acid to 100 mg/kg/day conjugated linoleic acid (Page 8 line 28-page 9 line 2). The dose is administered by way of tablet/pill thus anticipating an oral administration route (Page 8, lines 8-11 and claim 8). Menard et al. disclose the CLA can be readily incorporated in a dose-dependent manner into the tissues of animals consuming diets containing CLA thus anticipating instant claim 13 (Page 6, lines 19-22). Menard et al. disclose rheumatoid arthritis as a factor affecting human articular cartilage (Page 6, lines 23-30). The Examiner interprets this to mean that the method of treating rheumatoid arthritis is meant for human articular cartilage and thus reads upon instant claims 7-10.

Claim Rejections - 35 USC § 102

Claims 1-5 and 7-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Horrobin et al. (US 5,603,959).

Horrobin et al. disclose a method of treating rheumatoid arthritis comprising administering to a person in need of such treatment comprising an NSAID chemically linked to linoleic acid (Claims 7, 11 and 14).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cook et al. (US 6,077,868) in view of Watkins et al. (Journal of the American College of Nutrition 2000, 19(4), 478S-486S).

Cook et al. teach a method for reducing cyclooxygenase 2 mediated inflammation in an animal comprising the step of delivering into the animal an amount of a conjugated linoleic acid effective to reduce the inflammation (claim 7); a method for selectively inhibiting cyclooxygenase 2 activity in an animal having cyclooxygenase 2 activity comprising the step of administering to the animal an amount of a conjugated linoleic acid effective to reduce the activity of cyclooxygenase 2 (claim 1); the method

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wherein the administration step comprises a method selected from the group consisting of oral delivery, intramuscular injection, intravenous injection, transdermal delivery and transmucosal delivery (claim 2); the method wherein the animal is a human (claim 4); the method wherein the conjugated linoleic acid is selected from the group consisting of an 18:2(9c,11t) isomer, an 18:2(9t,11c) isomer, an 18:2(10c,12t) isomer, an 18:2(10t,12c) isomer, a bioactive ester thereof, a salt thereof, and a mixture thereof (claim 5); and a method wherein the CLA is delivered in a dosage of between 1 mg/kg and 1000 mg/kg body weight of the animal (claim 6). An appropriate amount of CLA in the diet is in the range of 0.1% to 5% by weight preferably 0.2% to 0.5% by weight in the diet (Column 3, lines 21-27).

Cook et al. do not expressly disclose a method of treating diseases (rheumatoid arthritis) or conditions caused by type III hypersensitive reactions in a human or non-human animal, the method comprising the step of administering to the animal a member selected from the group consisting of a conjugated linoleic acid (CLA) and a substance which is converted in the animal to CLA in an amount effective to reduce inflammation caused by the type III hypersensitive reactions in the animal.

Watkins et al. teach that anti-inflammatory diets are associated with decreased pathogenesis of rheumatoid arthritis, reduced inflammatory diseases and lowered cancer risk (Page 483S, Summary). Watkins et al. assert that multiple lines of evidence indicate that up-regulation of COX-2 contributes to inflammation (Page 483S, Summary). Watkins et al. state that the beneficial anti-cancer effect of CLA is likely linked to down-regulation of COX-2 activity (Page 484S, left column last paragraph).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to administer CLA, a down regulator of COX-2, to an animal for the purpose of treating rheumatoid arthritis to produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Watkins et al. suggest that research would lead to control of inflammatory bone joint disease (rheumatoid arthritis). In addition, the practice of the invention of US 6,077,868 would intrinsically treat rheumatoid arthritis.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the combined teachings of the cited references.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5,804,210 disclose methods of administering CLA to an animal.


No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

EVA



JOHN PAK
PRIMARY EXAMINER
GROUP 161